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Remarks

Claims 1, 3-11, 15-18, and 23-95 were initially pending in the subject application. In response to a restriction requirement, claims 45-83 and 89-95 were elected for examination on August 30, 2002. Applicant hereby affirms the election of the Group IV claims for examination in the current application. Certain of the claims have been amended and support for these amendments may be found, for example, at page 8, lines 12-20; page 12, lines 14-22; page 18, about lines 20-21; and page 19, lines 14-18. The undersigned respectfully submits that these amendments do not introduce new matter and favorable consideration of the claims, as now presented, is respectfully requested.

Applicants submit herewith a formal drawing for Figure 1, as required by the Notice of Draftsperson's Patent Drawing Review that accompanied the Office Action. In order to comply with the Draftsperson's requirements, Applicant has removed the descriptive matter from Figure 1 and, by the above amendment, has included it as part of the description of Figure 1 in the specification.

Claims 47, 48, 51, 52, 66, 67, and 69-71 have been rejected as being indefinite for use of the term "derived from" in claims 47, 48, and 51. Applicant appreciates the Examiner's suggestion and has amended these claims to recite instead "obtained from." Claims 58, 71, and 73 were also rejected as being indefinite for use of the term "and/or" in the claims. By the above amendments, the term "and/or" has been removed from these claims. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 58 and 60 have been rejected as being indefinite for use of the term "L-glycine" in the claims. Applicants have amended the claims and respectfully request withdrawal of this rejection. Claims 74-77 have been rejected as being indefinite for use of the term "any combination of (a) through (j)." Applicant has amended the claims to delete this term.

Claims 78-79 have been rejected as being indefinite because of the use of the term "biochemically key components that pharmacodynamically continue bonding effects. . . disease tissue." Applicant has amended the claims, as shown above, to remove reference to "biochemically key" and "continue bonding effects." Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 89 has been rejected as being indefinite because the peptides, polypeptide, proteins, medicants or tissues recited in the claim are not properly identified. Applicants have amended this

claim to more clearly define the peptides, polypeptides, proteins, tissues and medicants recited in the claim. Support for this amendment can be found at page 11, lines 17-22 through page 13, line 8.

Claims 45-54 and 74 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Garson *et al.* (U.S. Patent No. 5,753,211). The Office Action argues that the reference teaches the claimed composition, for treating nails, comprising collagen, cystine, phospholipids, vitamins, and other active agents (pointing to column 3, lines 17-26 of the specification of the '211 patent). Applicant submits that the reference fails to anticipate the claimed invention and respectfully traverses the rejection.

It is well settled law that, to anticipate a claim, the reference must teach an identical invention that is shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Additionally, a claim is anticipated only if each and every element, as set forth in the claim, is taught by the reference. In the case of the instant invention, Applicant respectfully submits that the reference fails to meet the limitations of the claimed invention.

For example, the '211 patent fails to teach "at least one optically pure essential L-amino acid". While the reference teaches the inclusion of cystine in the compositions of the reference, there is no mention or teaching of "optically pure L-cystine". Indeed, it is respectfully submitted that one skilled in the art would have recognized the designation of cystine to be indicative of a racemic mixture of cystine as opposed to an optically pure enantiomer of cystine that would be designated as D-cystine or L-cystine. Accordingly, it is respectfully submitted that the reference fails to anticipate the claimed invention because it fails to teach each and every element of the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

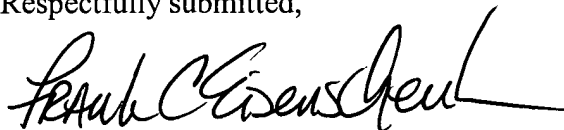
Applicant further submits that the reference is improperly applied against a variety of claims in the subject application. For example, claims 59-64, 72, 73, 75, 77, and 79 contain limitations that are not taught by the '211 patent (*e.g.*, compositions comprising optically pure L-amino acids such as glycine, L-alanine, L-leucine, L-valine, L-methionine, or gamma butyric acid). Additionally, the reference fails to teach a composition that contains a sterile vehicle (as set forth in claim 65). Applicant, thus, respectfully requests that the rejection be withdrawn as applied to these claims as well.

The Office Action has also rejected claims 55-57, 59, 61-65, 68, 72, 73, 82, and 83 for depending from a rejected claim. Applicant respectfully submits that these claims are not anticipated by the '211 patent and respectfully request reconsideration and withdrawal of the rejection.

In view of the foregoing remarks and the amendments to the claims, Applicant believes that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Marked-Up Version of Amended Specification Paragraph
Marked-Up Version of Amended Claims
Formal Drawing of Figure 1

Marked-Up Version of Amended Specification Paragraph

Figure 1 is a schematic drawing of a liver illustrating the locus of congenital biliary atresia disease being close to the location of stem cells and in approximately the area of believed therapeutic activity. Biliary atresia is evidenced by a sheet of periductular inflammation and fibrosis. Also shown on this H&E slide is extensive periductule inflammation. This inflammatory obstruction also prevents re-anastomosis of the biliary ductules diagrammatically illustrated here by superimposing the histopathology of biliary atresia upon the normal microscopic anatomy of the liver.

Marked-Up Version of Amended Claims**Claim 47. (Amended):**

The therapeutic composition or anti-inflammatory medicament according to claim 45, wherein said extracellular matrix compound is obtained~~derived~~ from cellular or tissue sources.

Claim 48. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 45, wherein said polar surface active lipid is obtained~~derived~~ from cellular or tissue sources.

Claim 51. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 45, wherein said optically pure essential L-amino acid is obtained~~derived~~ from cellular or tissue sources.

Claim 58. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 55, wherein said amino acids are selected from the group consisting of: glycine, L-alanine, L-leucine, L-isoleucine, L-threonine, L-cysteine, L-methionine, L-cystine, L-serine, ~~and/or~~ L-valine, or and any combinations thereof.

Claim 60. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 59, wherein said amino acids are ~~L~~-glycine, L-alanine, L-leucine, and L-valine.

Claim 71. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 70, wherein said molecular bonding forces are electron affinity, van der Waals forces, ~~and/or~~ zwitterionic.

Claim 73. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 72, wherein said molecular bonding forces are electron affinity, van der Waals forces, and/or zwitterionic.

Claim 74. (Amended):

The composition according to claim 45, further comprising one or more of the following: (a) at least one mineral; (b) at least one vitamin; (c) at least one antioxidant; (d) omega-3 oil(s); (e) zinc; (f) zinc oxide; (g) vitamin A; (h) chondroitin sulfate; (i) cartilage; or (j) collagen; ~~or any combination of (a) through (j).~~

Claim 75. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 59, further comprising one or more of the following: (a) at least one mineral; (b) at least one vitamin; (c) at least one antioxidant; (d) omega-3 oil(s); (e) zinc; (f) zinc oxide; (g) vitamin A; (h) chondroitin sulfate; (i) cartilage; or (j) collagen; ~~or any combination of (a) through (j).~~

Claim 76. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 48, further comprising one or more of the following: (a) at least one mineral; (b) at least one vitamin; (c) at least one antioxidant; (d) omega-3 oil(s); (e) zinc; (f) zinc oxide; (g) vitamin A; (h) chondroitin sulfate; (i) cartilage; or (j) collagen; ~~or any combination of (a) through (j).~~

Claim 77. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 73 further comprising one or more of the following: (a) at least one mineral; (b) at least one vitamin; (c) at least one antioxidant; (d) omega-3 oil(s); (e) zinc; (f) zinc oxide; (g) vitamin A; (h) chondroitin sulfate; (i) cartilage; or (j) collagen; ~~or any combination of (a) through (j).~~

Claim 78. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 71, wherein said composition provides ~~biochemically key components~~ biochemical components that pharmacodynamically ~~continue bonding effects in aid~~ in reorganization, regrowth, and regeneration of normal tissue or diseased tissue.

Claim 79. (Amended):

The therapeutic composition or anti-inflammatory medicament according to claim 73, wherein said composition provides biochemically ~~key components~~ that pharmacodynamically aid ~~continue bonding effects in~~ the reorganization, regrowth, and regeneration of normal tissue or disease tissue.

Claim 89. (Amended):

The therapeutic composition or anti-inflammatory medicant according to claim 45, wherein said composition or medicant mimics amino acid ratios found in healthy or normal ~~contains amino acids corresponding to the ratios of amino acid components in~~ peptides, polypeptides, proteins, medicants or tissues.